

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Sean P. Selover et al.

Application No.: 10/711,704 – Conf. No. 5703

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Entitled: METHODS AND DEVICES FOR
MINIMALLY INVASIVE SPINAL
FIXATION ELEMENT PLACEMENT

Docket No.: 101896-283 (DEP-5154CIP)

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I. REAL PARTY IN INTEREST

The real party in interest is DePuy Spine, Inc., a Johnson & Johnson company. DePuy Spine, Inc. of Raynham, Massachusetts derives its rights in this application by virtue of an assignment of the application by the inventors to DePuy Spine, Inc. as recorded at Reel 016148, Frame 0415.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-17 are currently pending in the present application, Serial Number 10/711,704. According to the Office Action mailed on October 22, 2007, claims 1-17 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,179,225 to Shluzas et al.

Accordingly, claims 1-17 are subject to appeal.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the Office Action mailed on October 22, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 recites a minimally invasive surgical method which includes, as shown for example in FIGS. 5A-5D of the pending application, forming an incision (62) through tissue located adjacent to a vertebra (60) in a patient's spinal column, identifying a muscle plane (see FIG. 5A), and inserting a substantially planar blunt tip (206) of a tool (200) (shown in greater detail in FIGS. 5F-5G) through the incision (62) while manipulating the blunt tip (206) along the muscle plane extending between the incision (62) and the vertebra (60) to separate the muscles (LT, M). As described in the specification, the claimed method can be utilized "to separate the longissimus thoracis and multifidus muscles, thereby exposing the facet and the junction of the transverse process and superior articular process." Para. [0051]. More specifically, the specification provides that "after the percutaneous incisions 62a-f are formed, as previously described, the blunt member 206 of the dissection tool 200 may be inserted through an incision 62. The incision may be deep enough to allow the fat layer between the longissimus thoracis and multifidus muscles to be located. Once

located, the tool 200 may be manipulated to separate or split the longissimus thoracis and multifidus muscles, thereby exposing the facet and the junction of the transverse process and superior articular process.” Para. [0055].

Independent claim 11 similarly recites a minimally invasive surgical method which includes making a first incision (62) in a patient, inserting a blunt tip (206) of a tool (200) through the first incision (62) and manipulating the blunt tip (206) to create a first pathway from the first incision (62), between a muscle plane, to a first site on a first vertebral body (60). The method of claim 11 further recites, as shown for example in FIG. 5E, advancing a guide wire (64) through the tool (200) to position a distal end of the guide wire adjacent the first site (60). As described in the specification, this step allows for the tool (200) to be withdrawn thereby leaving the guide wire (64) at the surgical site (60) to serve as a guide for various additional devices which can now be delivered to the site (60) through the separated muscle plane thereby minimizing any muscle damage. See para. [0055].

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether the Examiner improperly rejected claims 1-17 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,179,225 to Shluzas et al.

VII. ARGUMENT

A. Rejection Pursuant to 35 U.S.C. 102(e) Over U.S. Patent 7,179,225 of Shluzas et al.

1. The Examiner’s Rejection Over Shluzas and the Scope and Content of the Prior Art

Claims 1-17 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent 7,179,225 of Shluzas et al. (“Shluzas”).

Shluzas discloses “an access device that provides an internal passage for surgical instruments to be inserted through the skin and muscle tissue of the patient P to the surgical site.” See col. 17, lines 16-19. As shown in FIGS. 2-6 of Shluzas, the access device (i.e., retractor) 20 “includes a proximal wall portion 22 that has a tubular configuration and a distal wall portion that has an expandable skirt portion 24. The skirt portion 24 preferably is enlargeable from a reduced profile configuration having an initial dimension 26 (illustrated in FIG. 2) and corresponding cross-sectional area, to an enlarged configuration having a second dimension 28 (illustrated in FIG. 4) and

corresponding cross-sectional area.” Col. 18, lines 26-33. As shown in FIG. 2, the distal portion of the access device 20 has a circular cross-section (i.e., not a blunt tip). In use, following delivery of the skirt portion 24 to the treatment site, the expandable skirt portion 24 can be moved to the enlarged configuration thereby enhancing a user’s access to the surgical site.

Shluzas teaches delivering the access device through muscle and to a surgical site as follows:

After the above-described location is determined, an incision is made at the location. A guide wire (not shown) is introduced under fluoroscopic guidance *through the skin, fascia, and muscle* to the approximate surgical site. *A series of dilators is used to sequentially expand the incision to the desired width, about 23 mm in one procedure, preferably minimizing damage to the structure of surrounding tissue and muscles.* A first dilator can be placed over the guide wire to expand the opening. The guide wire may then be removed. A second dilator, slightly larger than the first dilator, is placed over the first dilator to expand the opening further. Once the second dilator is in place, the first dilator may be removed. This process of (1) introducing a next-larger-sized dilator coaxially over the previous dilator and (2) optionally removing the previous dilator(s) when the next-larger-sized dilator is in place continues until an opening of the desired size is created in the skin, muscle, and subcutaneous tissue....

Shluzas, Col. 22, lines 22-39 (emphasis added). Once this incision is of a sufficient diameter, the access device (20) is disposed therethrough such that the distal portion of the device (20) is adjacent the surgical site. Once positioned as such, the expandable skirt portion (24) is expanded thereby further traumatizing the muscle adjacent the surgical site. Following such expansion, additional surgical instruments can be delivered to the surgical site via the access device. For example, as shown in FIGS. 51-55, an apparatus (3100) can be delivered through the access device for use in delivering a spinal fixation element to the vertebrae. See col. 38, lines 32-42.

2. ***Shluzas Does Not Disclose Each and Every Element of Appellant’s Claimed Invention***

a. *Independent Claim 1*

As indicated above, independent claim 1 recites a minimally invasive surgical method that includes identifying a muscle plane and inserting a substantially planar blunt tip of a tool through the incision while manipulating the blunt tip along the muscle plane extending between the incision and

the vertebra to separate the muscle. Shluzas does not teach or even suggest any of the recited method steps.

(i) "Identifying A Muscle Plane"

The Examiner argues that Shluzas discloses making an incision and inserting a guide wire, and that "[i]n order to perform this step, some regard to a muscle plane must be address by the surgeon to determine the location of the incision." Oct. 22, 2007 Office Action, p. 3. The Examiner thus argues that "identifying a muscle plane," as required by claim 1, is an inherent feature of Shluzas.

In order for a reference to inherently anticipate, the claimed limitation must be necessarily present in the disclosure. Shluzas method does not necessarily require that the muscle plane be identified. To the contrary, the method is performed without any regard to the muscle plane. Muscles are formed from bundles of fibers, and a muscle plane is a location at which two different muscles can be separated from one another. A muscle plane does not need to be identified in order to determine the location of an incision, or to insert a guide wire or other tool through the muscle. Typically, a surgeon forms the incision at a desired location above the desired surgical site. The incision is formed regardless of the muscle plane, as the incision is made in the tissue and not in the muscles underlying the tissue. While the surgeon may understand what muscles lie beneath the tissue being incised, the muscle plane is certainly not identified and there is no need to identify the muscle plane in order to form the incision, as suggested by the Examiner.

There is also no need to identify the muscle plane in order to insert the guide wire through the muscles. As explained at Col. 22, lines 22-43 of Shluzas, a guide wire is introduced through the skin, fascia, and muscle to the surgical site, then a series of dilators are used to sequentially expand the incision followed by placement of an access device (i.e., the retractor) for providing a pathway to the surgical site. Since the guide wire extends along a straight path and cuts through the muscles, the muscle plane is not identified. Shluzas simply lacks any teaching, literal or inherent, of a method that includes identifying a muscle plane.

(ii) "Inserting A Substantially Planar Blunt Tip ..."

The Examiner further argues that Shluzas discloses "inserting a substantially planar blunt tip of a tool through the incision while manipulating the blunt tip along the muscle plane extending

between the incision and the vertebra to separate the muscles,” as further required by claim 1. The Examiner asserts that the retractor, or the tool (3100) shown in Figures 51 and 52, can be considered to have a blunt end, and that the tool (3100) is inserted through the incision. The Examiner does not provide any support for the limitation that the tool be manipulated along the muscle plane to separate the muscles, but rather merely states that the retractor is “interpreted as that which aids in providing access separating the muscles.” *Id.* at p. 2.

At the outset, the retractor, as shown in Figures 2 and 3 for example, has a generally hollow cylindrical shape. The distal portion is expandable to provide increased access to a surgical site. No person having ordinary skill in the art would consider a hollow cylindrical body to be blunt. Blunt is generally understood to mean dull, not-sharp. A hollow cylinder certainly does not have a dull, non-sharp end. To the contrary, the cylindrical end could be considered to be sharp, as it would likely cut through tissue. With regard to the tool (3100) shown in Figures 51 and 52, while this tool could be considered to have a blunt end, the tool (3100) is not inserted through the incision and used to separate a muscle plane. Rather, the tool (3100) shown in Figures 51 and 52 is inserted through the retractor. (See col. 38, lines 32-42).

Regardless of whether Shluzas discloses a blunt tip tool, Shluzas does not teach or even suggest manipulating any tool along a muscle plane to separate the muscles. As previously explained above, Shluzas discloses inserting a guide wire through the muscles – not along a muscle plane formed between muscles – and dilating the muscles using a series of dilators inserted over the guide wire. The retractor is then inserted over the dilators. Since the guide wire is merely penetrated through the muscles, the guide wire is not inserted along a muscle plane. Moreover, there is no teaching or suggestion to manipulate the tool to separate the muscle plane and thus the retractor inserted thereover necessarily is not inserted along a muscle plane.

Shluzas simply does not contain any teaching to identify a muscle plane, much less to manipulate a tool to separate the muscles along a plane. The procedure disclosed by Shluzas is the exact problem Applicants’ invention improves upon. Insertion of a guide wire and a series of dilators directly through the muscles will necessarily damage the muscles (as the guide wire cuts through the muscle, and the dilators will tear the muscle apart). Applicants have discovered that a blunt tip tool can be used to carefully separate the muscles along a muscle plane, and that this minimizes trauma to the patient.

Shluzas is therefore deficient for several reasons, and thus cannot anticipate claim 1. Accordingly, claim 1 represents allowable subject matter.

b. Dependent Claims 2-10

The Examiner also rejects claims 2-10, which depend from independent claim 1, as being anticipated by Shluzas. In light of above, these claims also represent allowable subject matter at least because they depend from an allowable base claim. Additionally, dependent claims 2 and 6 provide further limitations clearly not disclosed by Shluzas. These additional distinctions are described below.

(i) Dependent Claim 2

Claim 2 depends from independent claim 1 and recites that the longissimus thoracis and multifidus muscles are separated. As described above, Shluzas does not disclose a method for separating, or even being capable of separating, any type of muscles in the process of delivering an access device to a surgical site. Therefore, Shluzas certainly does not teach separating the longissimus thoracis and multifidus muscles.

(ii) Dependent Claim 6

Claim 6 depends from claim 4 and recites that the method further includes removing the tool from the guide wire such that the guide wire extends between the incision and the vertebra. As the name entails, the Shluzas' access device (20) provides access to the surgical site. As such, it would not make sense to remove the access device (20) prior to removal of the guide wire. In fact, the Examiner has not provided any disclosure, teaching, or suggestion of this limitation anywhere in Shluzas. Thus, claim 6 further distinguishes over Shluzas.

c. Independent Claim 11

Independent claim 11 recites a minimally invasive surgical method that includes making a first incision in a patient, inserting a blunt tip of a tool through the first incision and manipulating the blunt tip to create a first pathway from the first incision, between a muscle plane, to a first site on a first vertebral body, and advancing a guide wire through the tool to position a distal end of the guide wire adjacent the first site. Like above, Shluzas does not teach or even suggest several of the recited method steps.

As discussed above with respect to claim 1, Shluzas fails to teach, literally or inherently, any method in which a tool is inserted between a muscle plane. As also discussed in relation to claim 1, Shluzas clearly does not disclose utilizing the *blunt tip* of a tool to separate muscle along the muscle plane. To the contrary, Shluzas teaches inserting a guide wire directly into the muscle. The guide wire will necessarily penetrate the muscle. There is simply no suggestion to insert any tool along a muscle plane, rather than through the muscle itself.

Shluzas is therefore deficient with respect to claim 11 as well, and thus Shluzas cannot anticipate claim 11. Accordingly, claim 11 represents allowable subject matter.

d. Dependent Claims 12-17

The Examiner also rejects claims 12-17, which depend from independent claim 11, as being anticipated by Shluzas. In light of above, these claims also represent allowable subject matter at least because they depend from an allowable base claim. Additionally, dependent claims 12, 14, 15, and 16 provide further limitations clearly not disclosed by Shluzas. These additional distinctions are described below.

(i) Dependent claim 12

Claim 12 depends from claim 11 and recites that the method further includes removing the blunt-tipped tool and advancing a first implant along the guide wire to the first site on the vertebral body. Shluzas' access device (20) would clearly not be removed prior to introduction of a first implant. As the name suggest, the access device (20) provides access to the surgical site. Therefore, it would not make sense to remove the access device (20) and then attempt to deliver an implant to the vertebra. This point is made clear at col. 45, lines 13-29 of Shluzas which describes delivering various implants through the access device.

(ii) Dependent Claim 14

Claim 14 depends from independent claim 11, and recites that the method further includes making a second incision in a patient, inserting a blunt tip of a tool through the second incision and manipulating the tool to create a second pathway from the second incision, between a muscle plane, to a second site on a second vertebral body, and advancing a guide wire through the tool to position a distal end of the guide wire adjacent to the second site.

As described in detail above, Shluzas does not disclose a blunt tip of a tool, much less inserting a blunt tip tool through an incision and manipulating the tool to create a pathway from the incision, between a muscle plane, to a site on a vertebral body. Thus, Shluzas certainly does not disclose performing these steps a second time, as required by claim 14, so as to provide access to a second surgical site.

(iii) Dependent Claim 15

Claim 15 depends from claim 14, and recites that the method further includes removing the blunt-tipped tool and advancing a second implant along the second pathway to the second site on the second vertebral body. As explained above in relation to claim 12, Shluzas does not teach removing the access device (20) prior to advancing an implant. In fact, it would not make sense to remove the access device (20) prior to delivering the second implant along the second pathway because the sole purpose of the access device is to provide access to the surgical site. Claim 15 therefore further distinguishes over Shluzas.

(iv) Dependent Claim 16

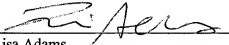
Claim 16 depends from claim 15 and recites that the method further includes placing a fixation element through the first pathway and coupling a portion of the fixation element to the first and second implants. In contrast, Shluzas does not disclose delivering a first implant via a first pathway, delivering a second implant via a second pathway, and coupling a fixation element thereto. Rather, as explained at col. 44, lines 59-63, Shluzas discloses the use of a single percutaneous access device capable of providing access to first and second bone anchors by expanding the distal portion of the access device. Thus, claim 16 further distinguishes over Shluzas.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,

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APPENDIX A: CLAIMS ON APPEAL

1. (Original): A minimally invasive surgical method, comprising:
forming an incision through tissue located adjacent to a vertebra in a patient's spinal column;
identifying a muscle plane;
inserting a substantially planar blunt tip of a tool through the incision while manipulating the blunt tip along the muscle plane extending between the incision and the vertebra to separate the muscles.
2. (Original): The method of claim 1, wherein the longissimus thoracis and multifidus muscles are separated.
3. (Original): The method of claim 1, wherein the incision is a minimally invasive percutaneous incision.
4. (Original): The method of claim 1, further comprising inserting a guide wire through a lumen extending through the tool.
5. (Original): The method of claim 4, wherein the guide wire extends into the vertebra.
6. (Original): The method of claim 4, further comprising removing the tool from the guide wire such that the guide wire extends between the incision and the vertebra.
7. (Original): The method of claim 6, further comprising delivering a spinal anchor along the guide wire and implanting the spinal anchor in the vertebra.
8. (Original): The method of claim 6, further comprising inserting a plurality of dilators over the guide wire to dilate tissue surrounding the guide wire.
9. (Original): The method of claim 8, further comprising inserting a cannula over the plurality of dilators and removing the dilators.
10. (Original): The method of claim 9, further comprising delivering a spinal anchor through the cannula.
11. (Original): A minimally invasive surgical method, comprising:
making a first incision in a patient;

inserting a blunt tip of a tool through the first incision and manipulating the blunt tip to create a first pathway from the first incision, between a muscle plane, to a first site on a first vertebral body; advancing a guide wire through the tool to position a distal end of the guide wire adjacent the first site.

12. (Original): The method of claim 11, further comprising removing the tool and advancing a first implant along the guide wire to the first site on the first vertebral body.

13. (Original): The method of claim 12, further comprising placing a fixation element through the first pathway in an orientation substantially parallel to a longitudinal axis of the first pathway, and coupling a portion of the fixation element to the first anchor.

14. (Original): The method of claim 11, further comprising:
making a second incision in a patient;
inserting a blunt tip of a tool through the second incision and manipulating the tool to create a second pathway from the second incision, between a muscle plane, to a second site on a second vertebral body; and
advancing a guide wire through the tool to position a distal end of the guide wire adjacent to the second site.

15. (Original): The method of claim 14, further comprising removing the tool and advancing a second implant along the second pathway to the second site on the second vertebral body.

16. (Original): The method of claim 15, further comprising placing a fixation element through the first pathway and coupling a portion of the fixation element to the first and second implants.

17. (Original): The method of claim 16, wherein the fixation element is inserted through the first pathway in an orientation substantially parallel to a longitudinal axis of the first pathway.

18-24. (Canceled).

APPENDIX B: EVIDENCE

None.

APPENDIX C: RELATED PROCEEDINGS

None.

APPENDIX D: CERTIFICATE OF AMENDMENT

Attached hereto.

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